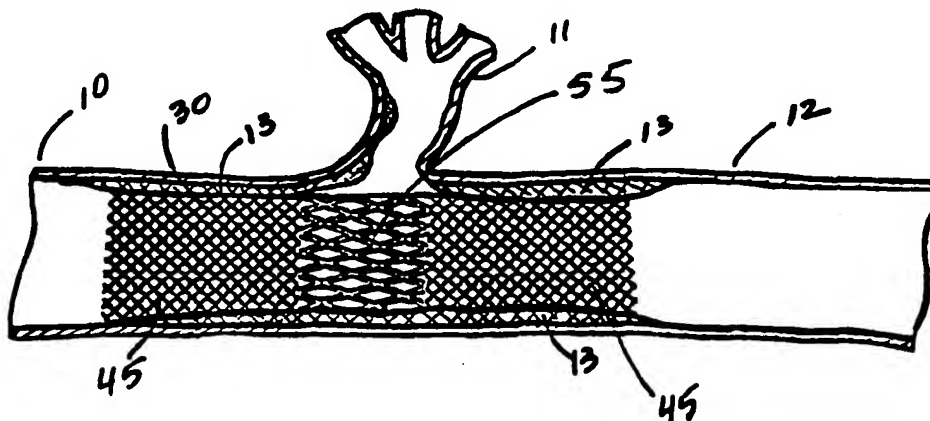




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | |
|--|----|---|
| (51) International Patent Classification ⁶ : A61F 2/06, 2/04 | A1 | (11) International Publication Number: WO 98/47447 (43) International Publication Date: 29 October 1998 (29.10.98) |
| (21) International Application Number: PCT/US98/08194 (22) International Filing Date: 21 April 1998 (21.04.98) (30) Priority Data: 60/044,163 23 April 1997 (23.04.97) US (71)(72) Applicant and Inventor: DUBRUL, William, R. [US/US]; No. 1 Uccelli Boulevard, Redwood City, CA 94063 (US). | | (81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report. |

(54) Title: BIFURCATED STENT AND DISTAL PROTECTION SYSTEM



(57) Abstract

A stent (30) comprising varying porosities for use in vessels (10) with bifurcations or side branches. The stent allows for scaffolding of the stenotic area (13) but still allows for flow into the side branches. A distal protection system (45) is also described.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|----|--------------------------|----|--|----|--|----|--------------------------|
| AL | Albania | ES | Spain | IS | Iceland | SI | Slovenia |
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav Republic of Macedonia | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | ML | Mali | TR | Turkey |
| BG | Bulgaria | HU | Hungary | MN | Mongolia | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MR | Mauritania | UA | Ukraine |
| BR | Brazil | IL | Israel | MW | Malawi | UG | Uganda |
| BY | Belarus | IS | Iceland | MX | Mexico | US | United States of America |
| CA | Canada | IT | Italy | NE | Niger | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NL | Netherlands | VN | Viet Nam |
| CG | Congo | KE | Kenya | NO | Norway | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NZ | New Zealand | ZW | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's Republic of Korea | PL | Poland | | |
| CM | Cameroon | KR | Republic of Korea | PT | Portugal | | |
| CN | China | KZ | Kazakhstan | RO | Romania | | |
| CU | Cuba | LC | Saint Lucia | RU | Russian Federation | | |
| CZ | Czech Republic | LI | Liechtenstein | SD | Sudan | | |
| DE | Germany | LK | Sri Lanka | SE | Sweden | | |
| DK | Denmark | LR | Liberia | SG | Singapore | | |
| EE | Estonia | | | | | | |

BIFURCATED STENT AND DISTAL PROTECTION SYSTEM

10

CROSS REFERENCE TO RELATED APPLICATION

The present invention is a continuation of provisional patent application serial No. 60/044,163, filed on and claiming priority of April 23, 1997, the full disclosure of which is
15 incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an implantable intraluminal device. More
20 specifically, the present invention relates to an implantable intraluminal device which is particularly useful for repairing or serving as a conduit for vessels narrowed or occluded by disease or for use in other body passageways requiring reinforcement or the like. Further, devices are disclosed in the present invention that can trap particulate that is loosened during interventional procedures such as stent or stent-graft placement, angioplasty, atherectomy,
25 etc.

2. Description of Background Art

Intraluminal devices or, more specifically, endovascular prostheses, are known for treating stenosis, stricture, aneurysm conditions and the like. Often these devices are
30 implanted via LIS (Least Invasive Surgery); whereby a small percutaneous access into the vessel is accomplished (usually remote to the diseased area). Alternatively, they are installed via an 'open surgery' approach. Advantages of the LIS approach (over conventional surgery) are significant from a cost as well as a patient care and recovery point of view. Intraluminal scaffolding devices such as stents are often used in combination with grafts and vice versa.
35 The graft is usually, but not always a textile/fabric type device that is used to cover a greater

5 area of the scaffolding as well as aid in neo-intimal formation after placement. Further, the two (stents and grafts) are often designed into one device called a stent-graft.

Each year about half a million Americans suffer a stroke in which obstruction or hemorrhage impairs the crucial flow of blood to the brain. About 150,000 of these stroke victims die, making stroke the third leading cause of death after heart disease and cancer, and
10 many more suffer permanent disability. According to the American Heart Association the cost of treating stroke exceeds \$25 billion a year.

Currently, approximately 180,000 Americans undergo a preventative operation to clear carotid arteries that carry blood to the brain. The operation, known as Carotid Endarterectomy (surgical removal of plaque from the carotid artery), usually requires patients
15 to stay in the hospital a few days, with typically a few weeks recovery time. This surgical procedure is increasing at an annual rate of greater than 20%.

A debate has arisen between vascular surgeons and "interventional" cardiologists and radiologists concerning the advantages of using of stents and/or stent-grafts to treat occluded carotid arteries compared with surgery. Stroke prevention operations/surgeries like
20 endarterectomies are performed by vascular surgeons in the United States at a cost of about \$1.5 billion per year. Efforts to use small stents in the brain to open and maintain patency in clogged arteries have triggered a fierce debate comparing the safety and efficacy of the medical techniques. Interventionalists claim that the scaffolding accomplished with stents is easier on the patient and the patient's pocketbook. Surgeons, on the other hand, are skeptical
25 of stenting in the carotid because of the potential for neurological complications as well as the potential for the stent to 'recoil' (return to a smaller diameter than when originally placed) some time after initial placement.

Various strategies have been devised and developed for vascular intervention in the treatment of Chronic Occlusive Disease (COD). Much of the critical occlusive disease
30 occurs at junctions (bifurcations) in the vasculature. Of particular interest are occluded carotid arteries and other bifurcated vasculature junctures.

A recent study funded by the NIH indicates the incidence of stroke can be reduced by 55% if the occluded carotid is treated by surgical intervention. This surgical procedure

5 sometimes allow minute pieces of plaque or blood clot (emboli) to travel into the brain causing at least temporary neurological damage, and often stroke or permanent neurological defects.

Various devices have been devised and used to dispense thrombolytic agents to the occluded vasculature and/or physically disrupt and dislodge the occluding thrombus. One
10 such catheter, described in US Patents 5,498,236, 5,380,273, and 5,713,848 by the present inventor was developed to penetrate and cross occluded portions within the vasculature, deploy an occlusion device distal to the occlusion to stop emboli from iatrogenic damage while clearing the occlusion/blockage. Although such catheters are adequate for removing occluding tissue in a vessel lumen, restenosis occurs unless balloon angioplasty or some sort
15 of scaffolding is left in place to prop the vessel open (e.g. stent or stent-graft). Scaffolding is becoming a preferred treatment, usually with balloon angioplasty (or sometimes without) because balloon angioplasty when used without some type of scaffolding has a tendency to have a temporary result.

Femoral artery access allows the interventionalist an easy, safe and less costly
20 approach to treat carotid stenosis with the least invasive trauma to the patient (other access is used as well). However, the need arises for a stent that can be deployed at a vascular "bifurcation" which does not occlude the side tributary (or side branch) at the bifurcation and still provide sufficient radial force to keep the vessel sufficiently open. In other words, a multi-porous or bifurcated stent or stent-graft that provides scaffolding at the vascular
25 bifurcation and still allows blood to flow in the main vessel as well as into the bifurcated tributary is desirable.

The prior art regarding scaffolding or 'propping open' of closed or stenotic vessels is extensive. Stents or stent-grafts for scaffolding singular lumens (without bifurcations) are numerous. Stents in the past decade have been one of the most prominent technologies
30 dealing with occlusive vascular disease. Additionally stents or stent-grafts for non-vascular occlusions such as urological, esophageal, biliary, etc. are prevalent as well. Patent number 5,383,925 by Schmitt et al describe a three dimensional braided soft tissue prostheses. In and of itself, this invention has similarities to the present invention because the present invention

5 also discloses braided prostheses (as well as a non-braided prosthesis). However, Schmitt et al does not address the subject of tributaries and bifurcations. Similarly, patent number 5,366,505 by Anderson et al describe a tubular medical prosthesis with knitted filaments with openings in between the filaments. This patent also does not address scaffolding of bifurcations. The stent or scaffolding intellectual property of this type that do not address
10 stenting of bifurcations is extensive and will not be further addressed in this patent.

Conversely, endovascular support devices that address this scaffolding or stenting of bifurcations although much less common than the aforementioned non-bifurcated stents or stent-grafts are also prevalent in the market of stents as well in the patent theatre. For example patent number 5,718,724 by Goicoechea et al describe a bifurcated endoluminal
15 prosthesis and method of installing the device, whereby the stent is configured into a one or two part Y configuration. In an analogous patent, number 5,632,763 by Glastra et al; the bifurcated stent in this patent is also an Y shaped scaffold. In these and similar Y shaped/configured bifurcated stents, the stent is designed to be placed in the entire bifurcation or Y. This enables scaffolding of the entire junction of all three tributaries.

20 However, there are situations where only the main vessel of the tributary is required to be stented. Such appears to be the case of stenting the bifurcation of the carotid artery. Thousands of linear (as opposed to Y stents) stents have been placed without FDA approval in the U.S. in this bifurcated carotid area. In these cases, a stent is placed into the common carotid artery and further into the internal carotid artery. The stent is placed across the
25 external carotid artery. These stents have walls with a very 'open' structure in that they are braided stents but have large enough areas to allow blood to flow through the stent wall and into the external carotid artery or other side branch. These numerous implantations have been reported without significant complications however at the time of this invention, prospective and long-term studies have not been completed. Blood flow from the common
30 carotid artery and into the internal carotid artery appears to be more important due to the fact that the internal carotid artery feeds blood into the middle cerebral artery and other arteries of the brain. However, blood flow into the external artery is still important and has to pass through the stent wall. This is known as 'stent jail' because the blood has to pass through the

5 weaves/filaments of the stent. Because of this phenomenon, only stents with large openings between the filaments of the stent can be used. This creates another problem in that there is a direct correlation between the openings between the filaments (pics per inch) and the outward radial force that can be transmitted to the vessel wall. As this open space increases, the outward radial force of the stent decreases. Conversely as the openings decrease in size, the radial force increases. Hence it is the object of the present invention to obviate that disadvantage by designing a multi-porous stent for bifurcations that allow a sufficient outward radial force, but still allows flow into the tributary or side branch.

Patent number 5,607,444 by Lam describes an ostial stent for bifurcations that is different than the Y configuration in that it the main tubular body of the stent is seated into the side branch and has a flaring end that is attached into the main vessel thereby not obstructing flow of the main branch. This design may be useful for side branches, but does not address the main vessel.

As previously mentioned, emboli can become loosened during surgical endarterectomies and these emboli can have deleterious affects 'downstream'. This occurrence would appear to be increased with a LIS approach due to the fact that in an open procedure, the site of revision is in direct view so that these particulate should be more easily detected. Conversely in a LIS procedure the physician is dependent upon image intensification and his or her actual skill to not allow emboli from being dislodged and causing 'downstream', distal problems. Patent, No. 5,695,519, by Summers et al. describes a percutaneous filter for carotid angioplasty. This design disclosure appears to have merit, but by design, it has a membrane of filter material that is overlapping that increases its diameter prior to deployment and upon un-deployment. The present invention obviates this disadvantage of a larger diameter in that there are no overlapping filaments. Further, a cumbersome 'gun' is required with the Summer system. Even further, the system is used only with angioplasty, which, as previously mentioned has a temporary effect. Patent numbers 4,842,579 and 4,926,858 describe distal barriers associated with atherectomy devices. Atherectomy has fallen from favor due to its apparent lack of efficacy combined with the complexity of use as compared with stent or stent-graft placement. Certainly, these

5 devices have not been perfected nor attempted for use in the head in neck area. The
filter/trap/occluder device of the present invention is designed to be used alone without any
angioplasty, atherectomy device. Further, the present filter invention has been fabricated and
tested where diameters of the device are as small as .010 inches in diameter. With sizes this
small and smaller, use in the vasculature of the head, is now available. This area appears to
10 be the new and large frontier in the treatment COD. Further, the filter/trap/occluder system
of the present invention provides for a novel braiding technique (that is used in the bifurcated
stent or stent-graft as well) that allows for entrapment of particles and removal.

15

SUMMARY OF THE INVENTION

A "procedure" oriented system for carotid stenting is presented which reduces or
eliminates the stroke potential during stent placement by positioning a fragment
20 filter/trap/occluder downstream (distally) from where the stent is disposed within a bifurcated
blood vessel such as the common carotid artery. The stent or stent-graft can be positioned
and deployed with comfort knowing that any clot, tissue fragments, etc. (emboli) which are
mobilized during deployment of the stent will be trapped in the filter thereby preventing such
fragments from entering the brain vasculature and causing the aforementioned deleterious
25 effects.

Often the stenosis in the carotid occurs at the junction of the common, internal and
external carotid arteries. This point of bifurcation of the common carotid artery is difficult to
stent. The present invention includes both a single lumen, multi-porous stent and a bifurcated
stent, both of which are operable for stenting, the common carotid artery at its point of
30 bifurcation. The present invention is also useful for scaffolding (propping open) other
bifurcated areas of the body, both vascular and non-vascular.

5 It is an object of this invention to provide a stent for maintaining patency of two or more branches of a bifurcated blood vessel that may be positioned using LIS at the point of bifurcation. These stents or stent-grafts can also be placed with an 'open' surgery approach.

It is a further object of the invention to provide an intravascular catheter for deploying a stent.

10 It is yet a further object of the invention to provide a stent deployment catheter or guide wire having filter means thereon operable for trapping tissue fragments dislodged during interventional procedures such as stent or stent-graft placement, balloon angioplasties, thrombolysis, etc.

It is still a further object of the invention to provide a stent or stent graft for a
15 bifurcated blood vessel which does not substantially interfere with the flow of blood through side branch vessel.

The features of the invention believed to be novel are set forth with particularity in the appended claims. However, the invention itself, both as to organization and method of operation, together with further objects and advantages thereof may best be understood by
20 reference to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a two-dimensional schematic cross-sectional view of the common carotid artery bifurcated to form the external carotid and the internal carotid arteries with a stenosis
25 within both branches. Figure 1 is also interpreted as being any vessel within the body where a bifurcation exists. It does not represent only the common carotid artery.

Figure 2 is a three-dimension perspective of two particular scaffolds of the present invention. In these schematics, the scaffold (stent or stent-graft) is made from a flat ribbon type material.

30 Figure 3 is a two-dimensional illustration of the distal protection filter/trap/occluder that may be used prior to or with placement of the stent. Further this distal protection system can be used in any interventional procedure where distal protection is desired.

5 Figure 4 shows two-dimensional illustrations of the scaffolding described in the present invention. Figure 4 illustrates both a ribbon type multi-porous stent or stent-graft (4C & 4D) and a braided type multi-porous stent or stent-graft (4A & 4B).

Figure 5 shows the bifurcated vessel in accordance with Figure 1 wherein the filter is first inserted and then deployed in the vessel (5A). Further Figure 5 shows the un-deployed
10 stent or stent-graft being inserted into position (5B), deployed and then the filter system removed (5C).

Figure 6 shows the bifurcated vessel in accordance with Figure 1 wherein two guide wires are inserted into the main and branch vessel (6A), the bifurcated stent or stent-graft of the present invention is inserted into the bifurcated area (6B & 6C), deployed and then the
15 guide wires are removed (6D).

DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The vasculature comprising the common carotid artery is shown schematically in Figure 1. The common carotid artery 10 branches to form the external carotid artery 11 and
20 the internal carotid artery 12. The walls 13 of the common carotid artery and the internal carotid are shown in Figure 1 to be thickened, reducing the lumen diameter of the vasculature. This thickened wall is often referred to as a stenotic lesion of the vessel and inhibits flow through the vessel.

A guide wire 20 may be positioned within the stenosed lumen of the common,
25 internal and/or external carotid arteries (or other bifurcated vessel system) as shown in Figures 5A, 5B, 6A, 6B & 6C. In Figures 6A, 6B & 6C, two guide wires 20 have been placed. A stent, which can be placed in any bifurcated lumen within the body (e.g. vascular, gastrointestinal, esophageal, etc.), is referred to herein as a "multi-porous stent" and shown at
30 in Figures 2.4 & 5. Turning now to figure 3, the filter 40 comprises a braided structure that is attached to an inner mandrill or wire 42 and an outer tube 43. The braid 41 is attached to the distally to the inner wire 42 and proximally to the outer tube 43. This attachment is accomplished in many ways, welding, heat-staking, gluing, etc. In Figure 3A, the filter 40 is in the undeployed configuration. In Figure 3B, the filter 40 is in the deployed condition.

5 This is accomplished by moving the inner wire 42 with respect to outer tube 43 and can be shown by the arrow 44 in Figure 3B. This action causes the braid to be put into compression and forces it to expand in an outward direction as in Figure 3B. The filter 40 illustrated is one which has variable pics per inch. One way to fabricate this variable braid is described in Patent number 5,366,443 by Eggars et al. This principal is often referred to as MLIB (Multi-
10 Layer Interlocking Braid), but this variable braid configuration can be made other ways, only one of which is by merely compressing the braid in an asymmetrical fashion. Another way is to attach two different braids together during manufacturing. The stent or stent-graft 30 of Figures 4A, 4B, 5B & 5C may be manufactured using this variable braid technology. The filter 40 can be made from simple non-variable braid as well. In that situation, the filter 41 is
15 deployed in the vessel and may or may not allow flow through it. If particulate are dislodged during the procedure, they will be trapped from moving downstream and can be irrigated/aspirated/lysed/obliterated (removed) from the vessel prior to un-deploying the filter and removal of it. Alternatively, the distal part of the filter 41 can have a covering over it that allows only small particles pass that are not detrimental. This covering can be a porous
20 elastic membrane, other braid, film, filter, fabric, textile, etc. In any case, the filter 41 may have one pore size on the proximal side of the filter 41 and a smaller pore size on the distal end. This will allow particles to travel into the proximal pores (in the case of braid, the interstitial space between the filaments), become trapped inside the filter 41 and then upon un-deployment removed from the vessel and patient. Turning now to Figure 4A & 4B, the
25 multi-porous stent or stent-graft can be designed in a similar fashion to the MLIB filter 40 previously described. Alternatively, as with filter 40, this multi-porosity can be altered using fabric, membrane, etc. Further, it can be fabricated by attaching two different types of braided structure together during manufacturing. In Figures 3A, 3B, 4A & 4B, the smaller pore size is represented by 45 and 46 show the larger pore size. All stents 30 in can be metal
30 or non-metal, as can the filters/traps/occluders 41. In the case of a self-expanding stent or filter, the material may be shaped memory alloy (SMA, metallic or polymeric). It is important to note that in Figures 3 & 5, the filter/trap/occluder illustrated can also be the initial guide wire(s) 20 placed or they can be an additional filter/trap/occluder 40. This

5 filter/trap/occluder may be placed over the initially placed guide wire 20 whereby it will have an additional inner lumen. In that case, the inner mandrill 42, would be a tubular structure as well. Further, the filter/trap/occluder can be placed all by itself. Turning now to Figures 2A, 2B, 4C & 4D, the multi-porous stent illustrated there is made of flattened material or ribbon 50. The multi-porous characteristic is constructed by removing part of the ribbon material
10 from the ribbon 50. This removed material is illustrated as windows 51 and 52 in the drawings. In Figure 4, the windows 51 are longitudinally shaped with respect to the ribbon 50. In Figure 2B, the windows 52 are in a circular shape. It is recognized that the shape of these openings is not relevant to the present invention, as any shape will result in multi-porosity. The ribbon 50 can be made of metallic or non-metallic material. In the case of self-
15 expanding stents, the material may be made of shaped memory alloy (SMA, metallic or polymeric). The strip of SMA is wound into a helical shape having a small diameter dimensioned to fit within the vessel. When the stent material is a shape memory alloy (such as Nitinol, NiTi, Nickel-Titanium or other similarly acting material) it can be programmed so that when heated from a cool temperature (e.g. room temperature) to body temperature (37°C,
20 98°F) it will assume a programmed, expanded tubular shape shown in Figures 5C & 6D or as illustrated in Figures 2, 4A, 4C, 5C & 6D. The shape-memory stent or stent-graft (or filter) material is chosen such that the transition temperature between the smaller, deformed structure shown in Figures 2A, 2B, 3A, 4B, 4D, 5B, 6B and 6C and the large diameter tubular structure shown in Figures 2A, 2B, 4A, 4C, 5C and 6D occurs at or below body temperature
25 (or some other temperature differential that will facilitate the change in size). The change in shape of the SMA material can be accomplished by the body temperature (whereby it would need to be constrained until in position) or by an extraneous thermal source such as warmed saline or a thermal catheter or guide wire. It is well known to anyone skilled in the art that SMA may need an elevated temperature to effect its dimensional change, but it will retain
30 that changed configuration with a temperature lower than that required to create the change in the first place. In other words, the stent 30 or filter 41 may need some temperature higher than body temperature (37°C or 98°F) like 35°C or 110°F to expand, but will stay expanded with significant radial force at the lower body temperature. The stent 30 or filter 41 is

5 preferably coated with a medical grade substance having low thrombogenicity or other medicament that helps prevent deleterious effects that may accompany these procedures. Alternatively, the stent 30 may be coated with any of a variety of fabrics/textiles that allow tissue growth into it and/or other stabilization. Further, the stent 30 may be impregnated with radioactivity, monoclonal anti-bodies or a variety of other medicaments that may inhibit
10 restenosis or other deleterious effects that wish to be avoided. Even further, it is understood that use of the present invention can be used with image intensification (Fluoroscopy, Ultrasound, Intraluminal Ultrasound, etc.).

Further, the stent 30 can be deployed by means of a guide wire or by means of an intravascular balloon catheter used either alone or adapted to slide over a guide wire 20, as
15 will be discussed below. The stent 30 is advanced along the guide wire 20 until it is in position at the juncture between the common and the internal carotid arteries (or other bifurcated vessel) as shown in Figures 5 & 6. It is recognized that the filter 40 also referred to as Distal Protection System (DPS) may or may not be used in conjunction with the stent placement. A guide wire 20 only may be used with a stent delivery catheter 60.
20 Alternatively, a guide wire 20 and filter 40 and delivery catheter 60 could be used. Another alternative would be the filter 40 and the stent 30 only could be used. Further, filter 40 and catheter 60 alone could be used.

At this point (when SMA is used), the stent 30 is permitted to warm to body temperature whereupon the stent undergoes a shape transformation as shown in Figure 5C or
25 6D. Alternatively, as mentioned above, additional thermal energy could be delivered to that area. Even further, SMA may not be used and the stent 30 could be deployed using an inflatable balloon (not shown) or other outward radial force component to enlarge the stent 30. The increased diameter of the stent holds the carotid artery (or other vessel) open at the juncture between the internal and common carotid arteries (or other vessel). A portion of the
30 stent 55 or 46 is preferably more permeable to flow than the remaining portion of the stent 45. This may be accomplished by aligning the windows 51 or 52 in the stent 30 such that upon enlarging the stent, the holes are preferably positioned with respect of the external carotid artery (or other side branch). Alternatively in the case of Figure 5B and 5C, the

5 multi-porous stent will be positioned so that the larger pores 55 are oriented to the side branch. The guide wire and/or catheter are then removed and the stent remains in position until no longer needed.

Another approach to maintaining patency at the point of bifurcation of the carotid is
10 by deploying a bifurcated stent. The bifurcated stent 80 (Figures 6 B, C & D) can also be made self-expanding from a shape-memory alloy or balloon expandable. The bifurcated stent 80 may be conveniently positioned at the juncture by means of dual guide wires as shown in Figure 6. The pair of guide wires 20 are advanced through the common carotid artery (or
other vessel) until they reach the bifurcation point. One guide wire 20 is inserted and
15 advanced into the external carotid artery (or other side branch) whereas the other guide wire 20 projects further into the internal carotid artery (or other vessel). The bifurcated stent 80 is advanced along the guide wires 20 by an over-the-wire catheter 60 or similar device such that
when the stent 80 reaches the point of division at the juncture of the internal and external
carotid arteries (or other bifurcated vessel), the arms of the bifurcated stent 80 divides. This
20 division of the bifurcated stent 80 can be aided by using two filter/trap/occluders 40 because of the retention force that they may have due to their impinging against the wall of the vessel. This will have a tendency to anchor the wire 20 and keep it from pulling out. This
characteristic of the filter/trap/occluder is obviously of benefit elsewhere other than in Figure
6 and even outside the scope of the present invention. One arm of the bifurcated stent will
25 project into the internal carotid artery and the other arm into the external carotid artery with the main portion of the stent remaining in the common and internal carotid arteries (or other
bifurcated vessels). This is shown clearly in Figures 6B and 6C. After the stent is warmed in the case of a self-expanding stent or stent-graft (or otherwise enlarged) the guide wires 20
may be removed and the stent remains in position as shown in Figure 6D.

5 One such way of making the stent is to use flat wound wire 50 and coil it into a cylinder as shown in Figures 2, 4C and 4D. Prior to deployment and placement in the body, it would be longer and a smaller diameter than when deployed. Further, holes or windows 51 and/or 52 would be made in the flat part of the wire in such locations that when the stent is deployed and takes its shorter and larger diameter shape, the holes 51 or 52 would be oriented
10 in such a fashion so that the stent could be place in such a way that the windows 51 & 52 of the stent would be aligned with respect to the bifurcated tributary (or side branch) and hence allow flow into or out of that tributary. It is understood that although the drawings indicate windows 51 & 52 only along one side of the stent or stent-graft, it would be simple to design windows circumferentially around the scaffold that would simplify placement of the device
15 by the physician. Alternatively, the multi-porous stent could be simply constructed out of round or flat wire that is programmed to take a particular shape upon enlargement. In other words, the wire would be coiled small for insertion, but when enlarged, the coils would be oriented close together where there is no side branch, and the space between the coils could have an increased distance between them at the bifurcation or side branch. Then the space
20 would decrease or diminish altogether on the other side of the side branch and be nested closer against one another again. This configuration is not illustrated in the drawings, but is readily understood by anyone skilled in the art.

The multi-porous stent can be expanded for deployment with an expandable balloon (e.g. balloon expandable stent) affixed to an intravascular catheter 60 or could be fabricated
25 of a biocompatible shape-memory alloy (SMA, polymeric or metal). If it is made from a SMA, the stent would take a preferred shape when exposed to a temperature differential. This temperature differential could be from room temperature (70°F) to body temperature (98°F) or higher. Any convenient temperature differential could be employed to expand the stent. For example, hot saline ($\cong 105-115^{\circ}\text{F}$) could be injected into the lumen of the vessel

5 where the stent is positioned and ready for deployment to force the SMA stent to expand and deploy. The warmed stent would remain in position maintaining its expanded shape with the help of body temperature. This could be accomplished using a thermal guide wire or catheter as well. Further, SMA could be used in combination with balloon deployment.

Another stent design may employ a braided material to form the stent body, such that
10 the preferred lower porosity area has less braid (thread density) in the particular area and/or more dense braid in the area where flow or porosity is not required.

The CPS (Cerebral Protection System) or DPS (Distal Protection System) approach allows the interventionalist an easy, safe and less costly approach to treat carotid stenosis (or other bifurcated stenosis) in a least invasive manner. This is accomplished by first using a
15 guide wire filter to trap plaque or blood clots from traveling downstream and causing stroke, death, etc. However, the need arises for a stent that can be deployed at a "bifurcation" which does not occlude the tributary/side branch at the bifurcation. In other words, a multi-porous or bifurcated stent or stent-graft allows scaffolding to occur at the bifurcation and still allow blood to flow in the main vessel as well as into the bifurcated tributary.

20 To safely deploy a vascular stent, the physician must first gain access to the vascular lumen then advance the distal end of the filter guide wire through the vessel until the fragment filter is positioned distal to blood flow. The interventionalist then deploys the filter which is constructed such that it will allow blood to flow through it but will trap 2-300 micron particles (or other particulate size that may be detrimental). The guide wire filter is a
25 two-lumen system with a moveable braid on the distal end. Alternatively the braid could have an elastic membrane over it so that it occludes the vessel fully or partially. If full occlusion occurs (from a fully or partially sealed filter 41), the lumen could be 'washed' for particulate (emboli) similar to the way endarterectomies are washed before closing the artery. In this case the 'washing' would be done by flushing and irrigating the lumen and then with

5 subsequent aspiration. This 'washing' may be repeated. When the two-lumen (42 & 43) filter 40 structure is pulled with respect to each other, the braid folds out in a round, ellipsoid, cone shape, etc. configuration. One side of the braid (the proximal end) may have large interstitial spaces and the other half may have small spaces that will trap clots and plaque.

Once deployed, the interventionist then slides the catheter 60 with the multi-porous
10 stent 30 over the guide wire 40 and advances the stent into position proximal to the fragment filter 41. Once in place, the multi-porous stent is deployed by expanding a balloon (not shown) thereunder to force the stent wall to expand within the vessel and be in correct orientation to the bifurcated tributary or side branch. Alternatively the stent 30 could be enlarged using thermal energy. When the multi-porous stent is successfully deployed, the
15 guide wire filter is un-deployed into its original small orientation (with any clots or plaque particles trapped inside) and removed or otherwise obliterated.

Often a stent or stent-graft such as a braided stent is mounted on a catheter over an inflatable balloon. The stent is prevented from expanding until in proper position within the vessel whereupon the balloon is inflated, causing the braided stent to press against the intima
20 (inner wall of the vessel). The balloon and filter are then deflated and retracted respectively and the removed leaving the stent within the vessel (s). It is noticed that the filter/trap/occluder can also be mounted onto the deployment catheter as opposed to a separate device. Alternatively, balloon angioplasty can be accomplished prior to inserting the stent to allow for easier placement of the stent and a subsequent larger diametrical result.

25 An *in vitro* model of the bifurcated carotid was designed and fabricated and a multi-porous stent and delivery system were developed. The multi-porous stent was deployed in the bifurcated area and proved to adequately provide scaffolding to prop open the common-internal carotid junction as well as continue to provide flow to the external carotid artery.

5 What I claim is:

16

- 10 1. An improved radially expandable, tubular prostheses having a wall useful for repairing compromised section of a bifurcated vessel, the compromised section of the vessel occurring near the bifurcation, said bifurcation including at least one vessel branching off from said vessel, the prostheses being of the type having an elongated body with a proximal end and a
- 15 distal end, wherein the improvement comprises at least a portion of the body of said prosthesis being configured so that its wall has variable porosity when
- 20 in place in the vessel to allow for decreased obstruction to the side branch when placed in a bifurcated area.
- 25 2. The prosthesis of claim 1 wherein a construction of the prosthesis is flattened material in a coiled configuration with windows in the wall of the coiled wire to decrease porosity there when in place in the area of bifurcation and in contact with the wall of said body lumen to maintain the axial position of said prosthesis in said body lumen.
- 30 3. The prosthesis of claim 1 wherein a construction is variable braided weave of filament material, braided in such a way that the interstitial space between the braid varies to allow different porosities when in place in the area of bifurcation and in contact with the wall of said body lumen to maintain the position of said
- 35 prosthesis in said body lumen.
- 40 4. The prosthesis of claim 1 comprising only a single of round material wound into a cylindrical spiral that has varying distances between the coils so that a variable porosity exists.

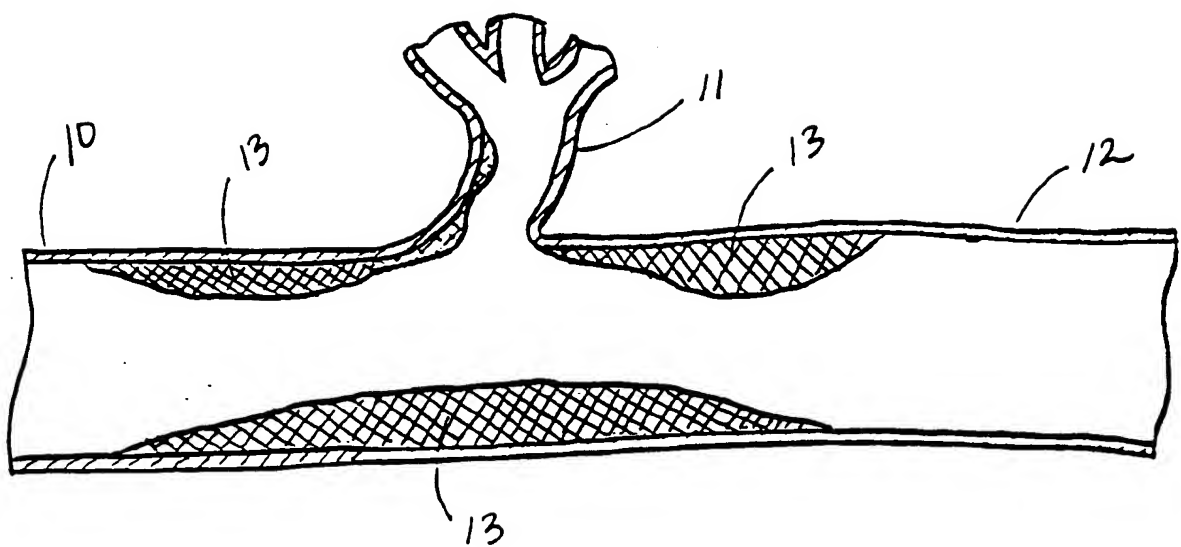
- 5 5. The prosthesis of claim 1 that is expandable to desired size by means of an
 internal expanding force that is an inflatable balloon.
6. The prosthesis of claim 1 that is expandable to desired size by means of a self-
 expanding force.
- 10 7. The prosthesis of claim 1 that is expandable to desired size by means of a self-
 expanding force and a balloon expandable force.
8. The prosthesis of claim 1 wherein the material used to make the prosthesis is
15 selected from the group consisting of tantalum and Nitinol, Dacron, wool, nylon,
 polyethylene, polyester, stainless steel alloy, titanium, Teflon or other alloy.
9. The stent of claim 1 wherein the prosthesis is coated with a coating comprising a
 textile fabric.
- 20 10. The prosthesis of claim 1 wherein said material used in the prostheses includes a
 drug.
11. The prosthesis of claim 1 wherein said material used in the prostheses includes
25 temporary energy dispersal that helps prevent restenosis.
12. A method for forming a endoluminal scaffold within a bifurcated area of a vessel
 wherein the bifurcated area includes a primary vessel portion and at least one
 secondary vessel portion branching off from said primary vessel portion, the
30 method comprising the following steps:
 positioning the scaffold having an interior lumen within said vessel by
 expanding the scaffold against said vessel wall;
 orienting a portion of the endoluminal scaffold so that an area of less porosity of

5 the scaffold is adjacent to the secondary branching vessel to decrease obstruction to that vessel.

13. A device for the removal of particles from a lumen within the body comprising:
an elongated, flexible, tubular member with a proximal end and a distal end, said
10 tubular member having a moveable inner, elongated member where the inner member is attached to the distal end of a braided structure and the outer tubular member is attached to the proximal end of the braided structure;
means for moving the inner member with respect to the outer tubular member
which simultaneously enlarges the distal, braided, structure so that it is
15 dimensioned to contact or nearly contact the inner tissue of a lumen in the body to inhibit particles from moving beyond the enlarged structure.
14. An improved device as in claim 13 where said braided structure has a smaller pore size one side as compared to the other.
- 20 15. An improved device as in claim 13 where said braided structure has an elastic membrane adjacent to the braided structure that limits the pore size to that of the membrane and larger.
- 25 16. An improved device as in claim 13 where said braided structure has a membrane adjacent to the braided structure that limits the pore size to that of the membrane and larger.
- 30 17. A method for forming an occlusion system within a lumen of the body to trap particles comprising the following steps:
inserting an elongated, flexible, tubular member with a proximal end and a distal

5 end. said tubular member having a moveable inner, elongated member where the
inner member is attached to the distal end of a braided structure and the outer
tubular member is attached to the proximal end of the braided structure;
moving the inner member with respect to the outer tubular member
which simultaneously enlarges the distal, braided, structure so that it is
10 dimensioned to contact or nearly contact the inner tissue of a lumen.

18. An improved radially expandable, tubular prostheses useful for repairing
compromised section of a bifurcated vessel, the compromised section of the
15 vessel occurring near the bifurcation, said bifurcation including at least one
vessel branching off from said vessel, the prostheses being of the type having
20 an elongated body with a proximal end and a distal end,
wherein the improvement comprises a scaffold that is a one-piece, forked
configuration where the fork is placed in the bifurcation using two guide
25 wires.

**FIG 1**

2/6

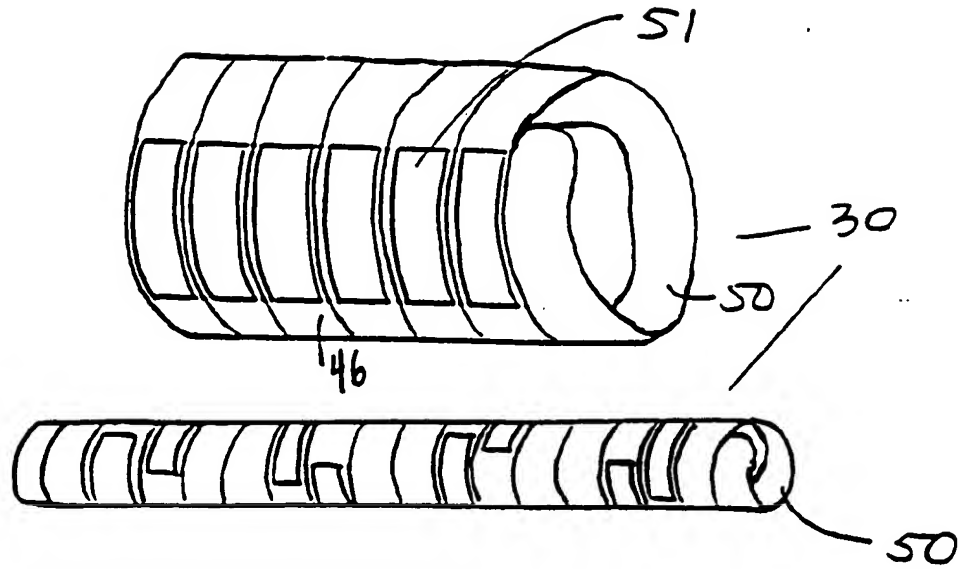


FIG 2A

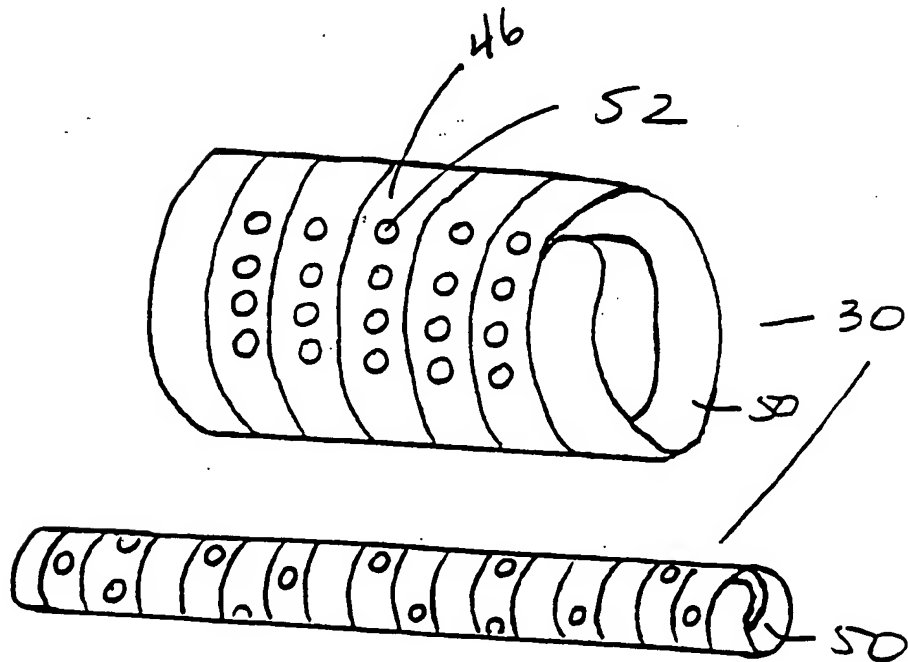
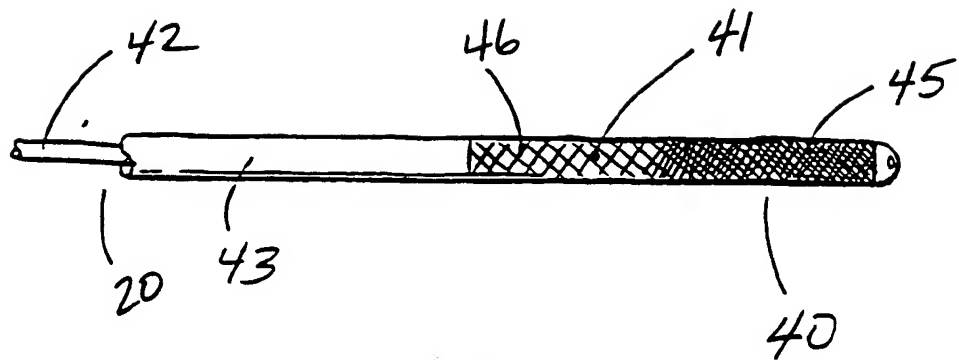
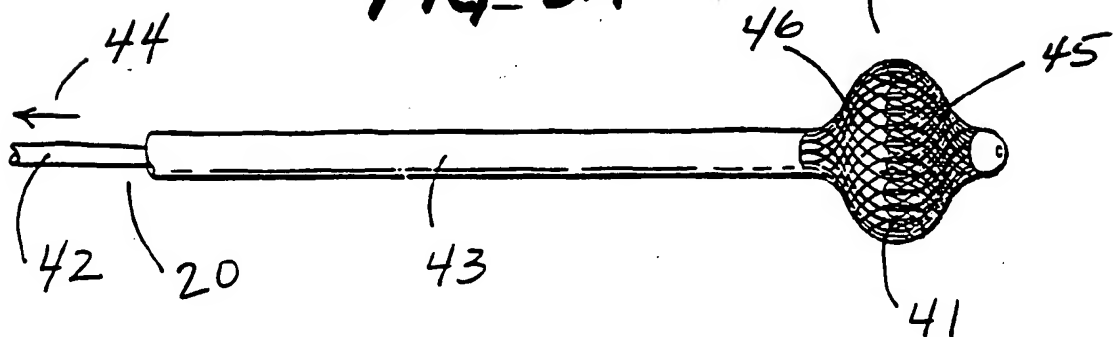


FIG 2B

**FIG-3A****FIG-3B**

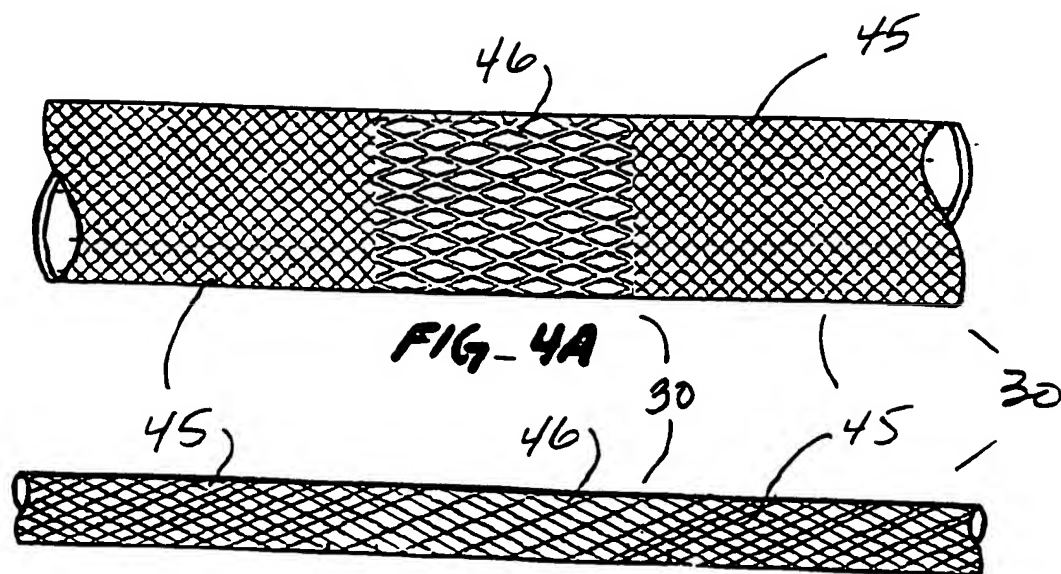


FIG- 4B

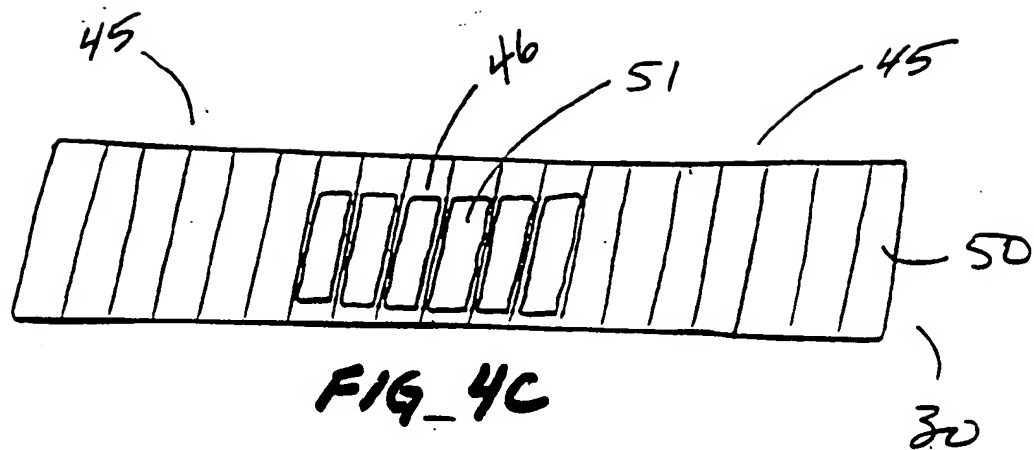


FIG- 4C



FIG- 4D

5/6

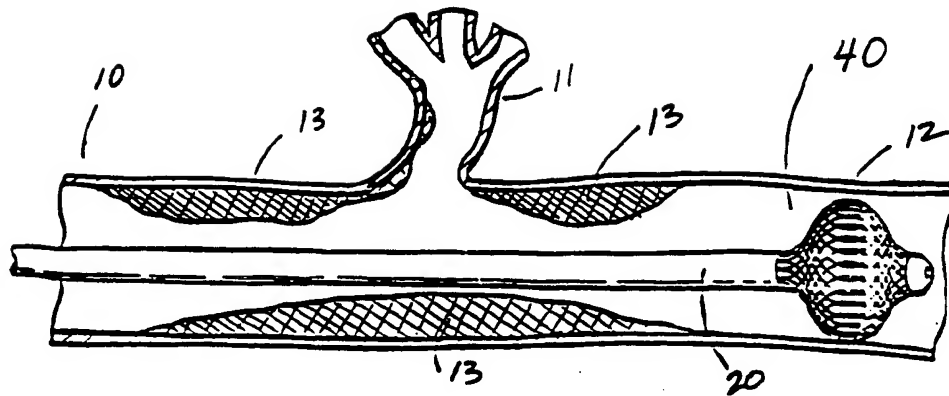


FIG 5A

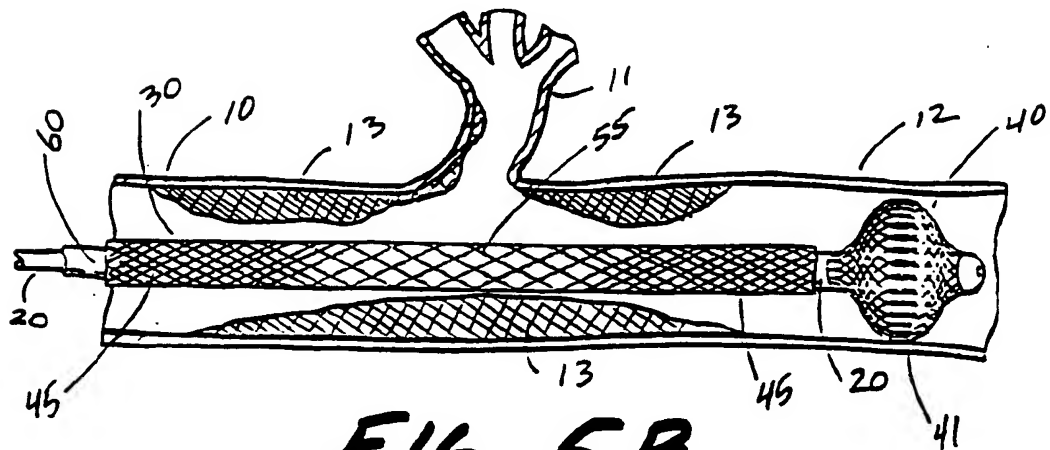


FIG 5B

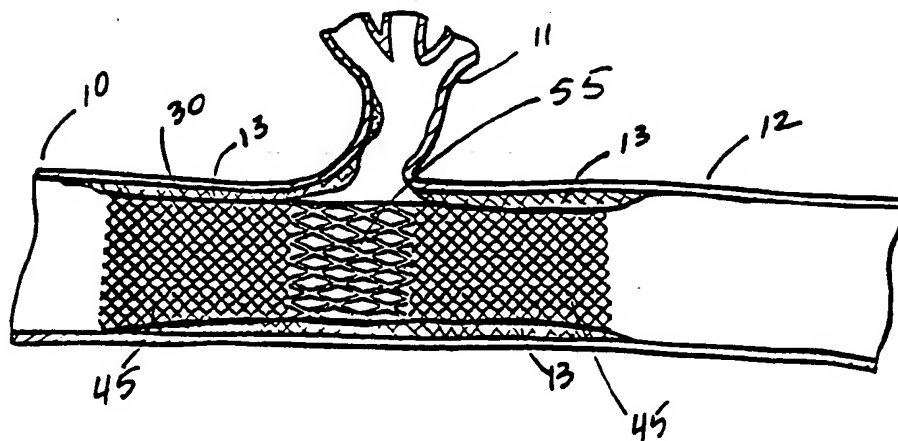


FIG 5C

6/6

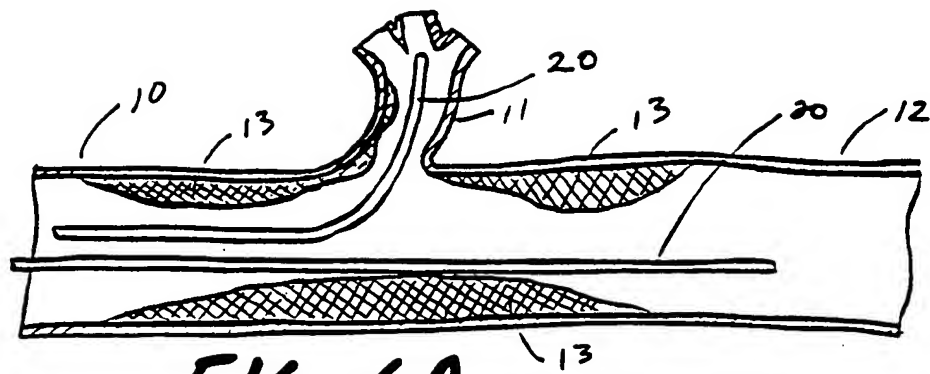


FIG 6A

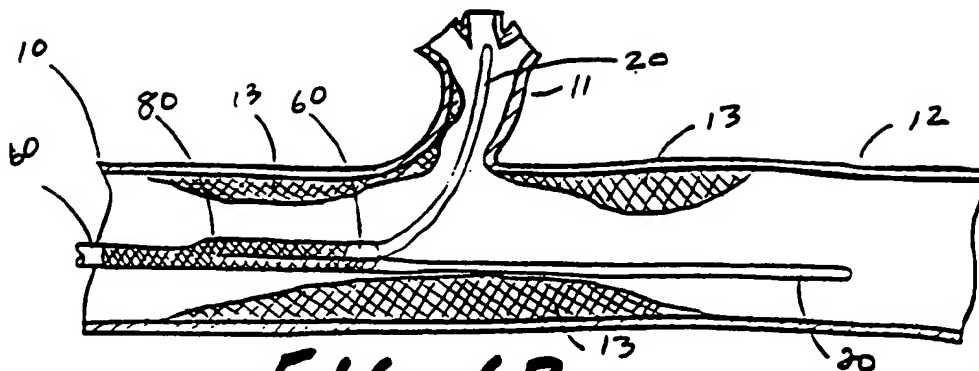


FIG 6B

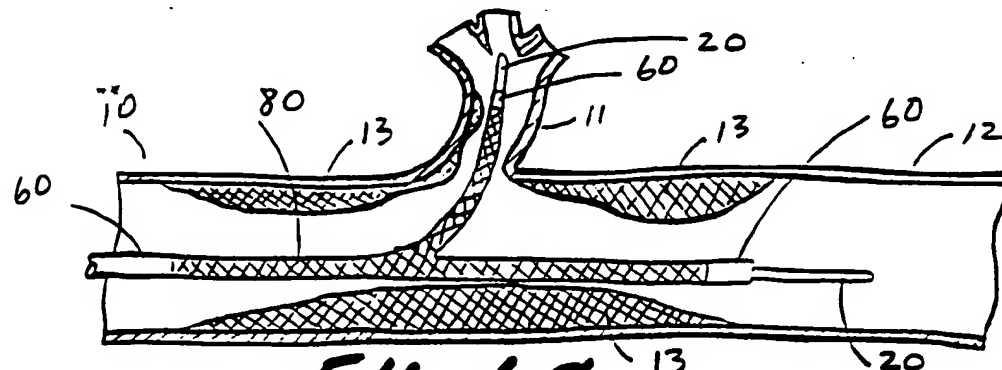


FIG 6C

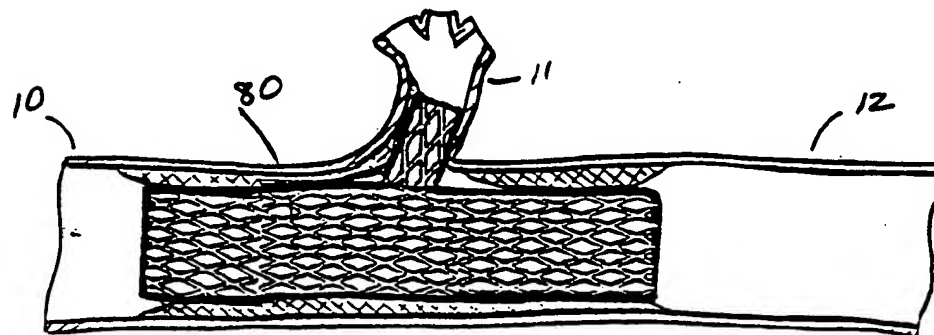


FIG 6D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/08194

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/06, 2/04

US CL : 623/1, 12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

search terms: stent, graft, pores, porosity, variable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|---------------------------|
| X | US, 5,383,892 A (CARDON et al) 24 January 1995, see Figures 1 and 2. | 1, 5, 8, 11-14, 16, 17 |
| X | US 5,562,725 A (SCHMITT et al) 8 October 1996, Figures 4 and 6, col. 7, lines 1-10 and 65-67, col. 8, lines 1-21, col. 6, lines 19-23. | 1, 3, 5-8, 11, 12, 14, 16 |
| X | US 5,603,722 A (PHAN et al) 18 February 1997, Figures 1c, 2c, 3c. | 1, 2, 4 |
| X | US 5,382,259 A (PHELPS et al) 17 January 1995, Figures 10, 11, 21 | 1, 3, 5, 8-14, 16, 17 |
| X | US 5,507,769 A (MARIN et al) 16 April 1996, Figure 2. | 18 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | |
|---|--|
| * Special categories of cited documents: | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| *A* document defining the general state of the art which is not considered to be of particular relevance | *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| *B* earlier document published on or after the international filing date | *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | *A* document member of the same patent family |
| *O* document referring to an oral disclosure, use, exhibition or other means | |
| *P* document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

22 JUNE 1998

Date of mailing of the international search report

24 July 1998 (24.07.98)

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

TRAM A. NGUYEN

Telephone No. (703) 308-0804

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)